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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Mitchell et al			
Serial No.	:	09/941,492	Examiner	:	Janet Epps
Filed	:	July 29, 2001	Group Art Unit:		1635
For	:	METHODS AND COMPOSITIONS FOR USE IN SPLICEOSOME MEDIATED RNA *TRANS*-SPLICING			

RESPONSE TO RESTRICTION REQUIREMENT

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231

September 29, 2003
Date of Deposit

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September 29, 2003
Date of Signature

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the outstanding Office Action mailed March 28, 2003, please consider the following remarks.

REMARKS

Claims 1-39 are presently pending in this application and have been subject to restriction as follows:

I. Claims 1-12, 18-35 and 37-38, drawn to nucleic acid molecules, vectors, compositions and cells comprising a nucleic acid molecule, classified in class 435, subclass 325;

II. Claims 13-17 and 39, drawn to a method of producing chimeric RNA molecule in a cell, classified in class 435, and subclass 6; and

III. Claim 36, drawn to a method for inhibiting the expression of papilloma virus pre-mRNA, classified in class 435, subclass 375.

In support of the present restriction requirement, the Examiner has alleged that the subject matter of the pending claims represent distinct inventions.

In particular, the Examiner alleges that the inventions of Group I and Group II–III are related as product and process of use. The Examiner maintains that "the inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product." According to the Examiner, in the instant case the nucleic acid molecules, vectors and cells included in Group I can be used for the production of proteins encoded by the gene encoded by the nucleic acid molecules comprised within the recited vectors.

Additionally, the Examiner alleges that the inventions of Group I and II are unrelated. According to the Examiner, the inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of preparation,

different functions, or different effects. In the instant case, the different inventions are drawn to different methods comprising different objectives and reciting different method steps.

The requirement for restriction is respectfully traversed for a number of reasons. First, there is clearly a structural and functional relationship between the claims of Group I, II and III. Specifically, the claims of all three groups relate directly to compositions and methods for targeting *trans*-splicing to a papilloma virus pre-mRNA for the purpose of inhibiting expression of the papilloma virus pre-mRNA.

Second, contrary to the Examiner's contention the nucleic acid molecules, vectors and cells of Group I are not designed to be used for the production of proteins encoded by the claimed nucleic acid molecule. In fact, the claimed nucleic acid molecules of Group I have no use independent from their ability to mediate a *trans*-splicing reaction which results in the production of a chimeric RNA molecule (Group II claims) which results in inhibition of papilloma virus expression (Group III claims). In other words, the process for using the product as claimed **cannot** be practiced with another materially different product **and** the product as claimed **cannot** be used in a materially different process of using that product.

Moreover, Applicant's respectfully direct the Examiner's attention to the claims of U.S. Patent No:6,280,978 ("the '978 patent"), a patent to which the present application claims priority. The claims are attached herewith as Exhibit A. A review of the claims issued in the '978 patent demonstrates that the Patent and Trademark Office had previously determined that claims to compositions capable of targeting binding to a cystic fibrosis trans-membrane

conductance regulator pre-mRNA and methods for producing a chimeric RNA molecule in a cell utilizing such compositions were considered a single invention.

Finally, given the relationship between the subject matter encompassed by the pending claims of Groups I, II and III, Applicants assert that there would not be an undue search burden to examine the pending claims as a single group.

However, in order to be fully responsive to the requirement for restriction, Applicants elect, with traverse, the claimed nucleic acid molecules, vectors, compositions and cells of Group I. Withdrawal of the requirement for restriction and favorable consideration and allowance is earnestly solicited.

Respectfully submitted,

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